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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,952	04/16/2004	Inder Raj S. Makin	END5311USNP	8216

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EXAMINER	
FERNANDEZ, KATHERINE L	
ART UNIT	PAPER NUMBER
3768	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,952	MAKIN ET AL.	
	Examiner	Art Unit	
	KATHERINE L. FERNANDEZ	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13,14,16,17,19,20,22,23,25,26 and 28-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-11,13,14,16,17,19,20,22,23,25,26 and 28-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. The arguments in the Request for Reconsideration filed on May 2, 2008 were persuasive and the finality of the last office action is hereby withdrawn.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 9 and 28-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Hossack et al. (US Patent No. 6,171,248).

With regards to claims 1-3 and 9, Hossack et al. disclose an ultrasound medical system comprising an ultrasound transducer assembly having a longitudinal axis, having a distal end, and having: a) a first ultrasound transducer (22') disposed proximate the distal end and having a substantially-fully-cylindrical ultrasound-emitting outer exposed surface which is substantially coaxially aligned with, and outwardly-facing from, the longitudinal axis; b) a second ultrasound transducer (200) having a substantially-fully-cylindrical ultrasound-emitting outer exposed surface which is substantially coaxially aligned with, and outwardly facing from, the longitudinal axis; and c) a third ultrasound transducer (20') disposed longitudinally between (i.e. proximal) the first and second ultrasound transducers and having a plurality of planar transducer elements arranged to provide the third ultrasound transducer with an ultrasound-emitting outer exposed surface which is substantially-entirely planar (see Figure 5; column 7, line 41-column 8, line 24). The first and second ultrasound transducers have

a plurality of ultrasound transducer elements (column 3, line 52-column 4, line 13; column 7, lines 45-47).

With regards to claims 28-29, Hossack et al. disclose an ultrasound medical system comprising an ultrasound medical system comprising an ultrasound transducer assembly having a longitudinal axis, having a distal end, and having two ultrasound transducers, wherein one of the ultrasound transducers (22) has a substantially-fully-cylindrical ultrasound-emitting outer exposed surface which is substantially coaxially aligned with, and outwardly-facing from, the longitudinal axis, and wherein an other of the ultrasound transducers (20) is disposed longitudinally proximal to the one ultrasound transducer and has a plurality of planar transducer elements arranged to provide the other ultrasound transducer with an ultrasound-emitting outer exposed surface which is substantially-entirely planar (see Figure 1; column 3, lines 28-44). The one ultrasound transducer is disposed proximate the distal end (see Figure 1).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossack et al. as applied to claim 1 above, and further in view of Weng et al. (US Patent No. 7,063,666).

As discussed above, Hossack et al. meet the limitations of claim 1. However, they do not specifically disclose that the ultrasound-emitting outer exposed surface of the third ultrasound transducer is in its entirety has a substantially-cylindrically-focused shape or a substantially-spherically-focused shape. Weng et al. disclose an ultrasound transducer apparatus comprising a generally concave array of ultrasound transducer elements (column 3, lines 61-63). They disclose that the concave array system is much simpler and less costly than a conventionaly linear phased array system (column 4, lines 1-8). They further disclose that the concave geometry also requires smaller phase differences between transducer elements, thus reducing cross-talk and heating between elements, and further the geometry also reduces the affect of grating lobe problems during the beam-forming process (column 4, lines 1-8). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Hossack et al. to have their system to have a concave geometry, which would provide a substantially-cylindrically-focused shape or a substantially-spherically-focused shape, as taught by Weng, as a concave geometry is simpler and less costly than a linear array system, requires smaller phase differences between transducer elements, thus reducing cross-talk, and reduces the affect of grating lobe problems during the beam-forming process (column 4, lines 1-8).

6. Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossack et al. as applied to claim 1 above, and further in view of Fujio et al.. (US Patent No. 5,471,988).

As discussed above, Hossack et al. meet the limitations of claim 1. However, they do not specifically disclose that the first and second transducers are ultrasound-medical-treatment-only ultrasound transducers. Fujio et al. disclose an ultrasound medical system comprising an ultrasound transducer assembly having a longitudinal axis, having a distal end, and having: a) a first ultrasound transducer (479) disposed proximate the distal end and having a substantially-fully-cylindrical ultrasound-emitting outer exposed surface which is substantially coaxially aligned with, and outwardly-facing from, the longitudinal axis (see Figures 64 and 67; column 53, lines 36-53); b) a second ultrasound transducer (479') having a substantially-fully cylindrical ultrasound-emitting outer-exposed surface which is substantially coaxially aligned with, and outwardly-facing from the longitudinal axis (see Figures 64 and 67; column 53, lines 36-53); and a third ultrasound transducer (478) disposed longitudinally between the first and second ultrasound transducers and having a plurality of planar transducer elements (see Figures 64-65 and 67; column 53, lines 36-53). The first ultrasound transducer (479) is disposed at the distal end, and the third ultrasound transducer (478) is disposed proximate the first (479) and second (479') ultrasound transducers (see Figures 64 and 67). The first and second ultrasound transducer (479,479') are ultrasound-medical treatment-only ultrasound transducers (column 53, lines 36-43). Further, Fujio et al. disclose an embodiment of their invention, in which they disclose that an ultrasound treatment transducer (i.e. the first and second transducers in the embodiment discussed above for instant claim 1) may be a single ultrasonic transducer or a plurality of ultrasonic transducers (column 30, lines 56-67). At the time of the invention, it would

have been obvious to one of ordinary skill in the art to have the first and second ultrasound transducers of Hossack et al. be ultrasound-medical-treatment-only ultrasound transducers and to have the first and second ultrasound transducers have only one ultrasound transducer element, as taught by Fujio et al., in order to provide ultrasonic therapy to tissue and Fujio teaches that a plurality of transducers and a single transducer are interchangeable and can serve the same purpose (column 30, lines 56-67).

7. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hossack et al. in view of Fujio et al. as applied to claim 6 above, and further in view of Makin et al. (US Pub No. 2003/0018266).

As discussed above, Hossack et al. in view of Fujio et al. meet the limitations of claim 1. However, they do not specifically disclose that the third ultrasound transducer is an ultrasound-medical-treatment-and-imaging ultrasound transducer. Makin et al. disclose an ultrasound medical system including an ultrasound transducer assembly which is insertable into a patient, which has a longitudinal axis, and which has a plurality of ultrasound transducers. They disclose that at least one of the transducers is an ultrasound imaging and medical-treatment transducer which allows monitoring during treatment (pg. 1, paragraph [0004]; pg. 6, paragraph [0065]; pg. 7, paragraph [0076]). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the third transducer in the system of Hossack et al. in view of Fujio et al. to be an ultrasound-medical-treatment-and-imaging ultrasound transducer, as taught by Makin et al., in order to monitor the ultrasound treatment (pg. 1, paragraph [0004]).

8. Claims 10-11, 13-14, 22-23 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossack et al. in view of Fujio et al., Makin et al. and Weng et al.

As discussed above, the combined references of Hossack et al. and Fujio et al. meets most of the limitations of claims 10-11 and 13-14 (i.e. ultrasound transducer assembly having first, second and third ultrasound transducers, planar transducer elements, first and second ultrasound transducers being ultrasound-medical-treatmetn-only ultrasound transducers, etc.). However, Hossack et al. in view of Fujio et al. do not specifically disclose that the third ultrasound transducer is an ultrasound-medical-treatment-and-imaging ultrasound transducer or that the ultrasound-emitting outer exposed surface includes at least a concave surface portion.

Makin et al. disclose an ultrasound medical system including an ultrasound transducer assembly which is insertable into a patient, which has a longitudinal axis, and which has a plurality of ultrasound transducers. They disclose that at least one of the transducers is an ultrasound imaging and medical-treatment transducer which allows monitoring during treatment (pg. 1, paragraph [0004]; pg. 6, paragraph [0065]; pg. 7, paragraph [0076]). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the third transducer in the system of Hossack et al. in view of Fujio et al. to be an ultrasound-medical-treatment-and-imaging ultrasound transducer, as taught by Makin et al., in order to monitor the ultrasound treatment (pg. 1, paragraph [0004]).

However, the combined references of Hossack et al., Fujio et al. and Makin et al. do not disclose that the ultrasound-emitting outer exposed surface includes at least a concave surface portion. Weng et al. disclose an ultrasound transducer apparatus comprising a generally concave array of ultrasound transducer elements (column 3, lines 61-63). They disclose that the concave array system is much simpler and less costly than a conventionaly linear phased array system (column 4, lines 1-8). They further disclose that the concave geometry also requires smaller phase differences between transducer elements, thus reducing cross-talk and heating between elements, and further the geometry also reduces the affect of grating lobe problems during the beam-forming process (column 4, lines 1-8). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of the combined references Hossack et al, Fujio et al. and Makin et al. to have their transducer assembly include a concave geometry, as taught by Weng et al., as a concave geometry is simpler and less costly than a linear array system, requires smaller phase differences between transducer elements, thus reducing cross-talk, and reduces the affect of grating lobe problems during the beam-forming process (column 4, lines 1-8).

As discussed above, Hossack et al. in view of Fujio et al. meets most of the limitations of claims 22-23 and 25-26 (i.e. ultrasound transducer assembly having first, second, and third ultrasound transducers, etc.). However, they do not disclose that the first and second ultrasound transducers are ultrasound-medical-treatment-and-imaging ultrasound transducers, and the third ultrasound transducer is an ultrasound-medical-treatment only ultrasound transducer. Further, they do not disclose that the ultrasound-

emitting outer exposed surface includes at least a concave surface portion. Makin et al. disclose that at least one of the transducers is an ultrasound imaging and medical-treatment transducer and that at least one of the transducers is an ultrasound medical treatment transducer (pg. 6, paragraph [0065]; pg. 7, paragraph [0076]). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system of Hossack et al. in view of Fujio et al. to have the first and second ultrasound transducers be ultrasound medical treatment and imaging ultrasound transducers and have the third transducer be an ultrasound-medical-treatment only transducer, as taught by Makin et al., in order to successfully apply and monitor ultrasound treatment (pg. 1, paragraph [0004]).

However, the above combined references do not disclose that the ultrasound-emitting outer exposed surface includes at least a concave surface portion. Weng et al. disclose an ultrasound transducer apparatus comprising a generally concave array of ultrasound transducer elements (column 3, lines 61-63). They disclose that the concave array system is much simpler and less costly than a conventionaly linear phased array system (column 4, lines 1-8). They further disclose that the concave geometry also requires smaller phase differences between transducer elements, thus reducing cross-talk and heating between elements, and further the geometry also reduces the affect of grating lobe problems during the beam-forming process (column 4, lines 1-8). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Hossack et al. in view of Fujio et al. and Makin et al. to have their transducer assembly include a concave geometry, as taught by

Weng et al., as a concave geometry is simpler and less costly than a linear array system, requires smaller phase differences between transducer elements, thus reducing cross-talk, and reduces the affect of grating lobe problems during the beam-forming process (column 4, lines 1-8).

9. Claims 16-17 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossack et al. as in view of Fujio et al. and Weng et al.

As discussed above, Hossack et al. meet most of the limitations of claims 16-17 and 19-20 (i.e. ultrasound transducer assembly having a longitudinal axis, first, second, third ultrasound transducers having a plurality of planar transducer elements, third ultrasound transducer is an ultrasound-medical-imaging only transducer etc.). However, they do not specifically disclose that the ultrasound-emitting outer exposed surface includes at least a concave surface portion, or that the first and second ultrasound transducers are ultrasound-medical-treatment-only ultrasound transducers. As discussed above, Fujio et al. disclose an ultrasound transducer assembly wherein the first and second ultrasound transducer (479,479') are ultrasound-medical treatment-only ultrasound transducers (column 53, lines 36-43). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the first and second ultrasound transducers of Hossack et al. be ultrasound-medical-treatment-only ultrasound transducers, as taught by Fujio et al., in order to provide ultrasonic therapy to tissue. However, they do not specifically disclose that the outer exposed surface includes at least a concave surface portion or that the surfaces of the ultrasound transducers in their entirety have a substantially cylindrically-focused or a

substantially spherically-focused shape. Weng et al. disclose an ultrasound transducer apparatus comprising a generally concave array of ultrasound transducer elements (column 3, lines 61-63). They disclose that the concave array system is much simpler and less costly than a conventionaly linear phased array system (column 4, lines 1-8). They further disclose that the concave geometry also requires smaller phase differences between transducer elements, thus reducing cross-talk and heating between elements, and further the geometry also reduces the affect of grating lobe problems during the beam-forming process (column 4, lines 1-8). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Hossack et al. in view of Fujio et al. to have their system to have a concave geometry, which would provide a substantially-cylindrically-focused shape or a substantially-spherically-focused shape, as taught by Weng, as a concave geometry is simpler and less costly than a linear array system, requires smaller phase differences between transducer elements, thus reducing cross-talk, and reduces the affect of grating lobe problems during the beam-forming process (column 4, lines 1-8).

10. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vaezy et al. (US Patent No. 6,716,184) in view of Weng et al. (US Patent No. 7,063,666).

Vaezy et al. disclose an ultrasound medical system comprising an ultrasound transducer assembly having a longitudinal axis, and having two ultrasound transducer each having a plurality of planar transducer elements arranged to provide each of the two ultrasound transducer with an ultrasound-emitting outer exposed surface, wherein one of the ultrasound transducers is disposed longitudinally proximal or distal to an

other of the ultrasound transducers, and wherein the one and the other ultrasound transducers are different types of medical-treatment-only type and medical-imaging-only type transducers (column 23, lines 58-67; see Figure 21). However, they do not specifically disclose that their system includes at least a concave surface portion. Weng et al. disclose an ultrasound transducer apparatus comprising a generally concave array of ultrasound transducer elements (column 3, lines 61-63). They disclose that the concave array system is much simpler and less costly than a conventionaly linear phased array system (column 4, lines 1-8). They further disclose that the concave geometry also requires smaller phase differences between transducer elements, thus reducing cross-talk and heating between elements, and further the geometry also reduces the affect of grating lobe problems during the beam-forming process (column 4, lines 1-8). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Vaezy et al. to have their system include a concave surface portion, as taught by Weng, as a concave geometry is simpler and less costly than a linear array system, requires smaller phase differences between transducer elements, thus reducing cross-talk, and reduces the affect of grating lobe problems during the beam-forming process (column 4, lines 1-8).

Response to Arguments

11. Applicant's arguments with respect to claims 1-30 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment filed on November 21, 2007 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE L. FERNANDEZ whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768